

REMARKS

Claims 1-8 and 15-18 are all the claims pending in the application. Non-elected claims 9-14 are canceled without prejudice to the filing of a Divisional Application thereon. The amendment cancels claim 4 and resubmits it as new claim 19, dependent from claim 2, in order to further clarify the present claimed invention. Claim 15 is canceled and resubmitted as new independent claims 20 and 21, in order to remove dependency from non-elected claims 12 and 13. Similarly, claim 18 is canceled and resubmitted as new independent claim 22, in order to remove dependency from non-elected claim 10. Claim 1-3, 5-8, and 16 are amended in order to further clarify the present claimed invention and to specifically define the subject matter of the invention.

Applicants respectfully submit that the amendments are fully supported and no new matter has been introduced, hence Applicants respectfully request entry of the same.

Effective U.S. filing date

Applicants are filing concurrently herewith a Request for Corrected Official Filing Receipt. The present application is a National Stage Application under 35 U.S.C. § 371 and thus, it is entitled to an effective U.S. filing date of March 24, 1999. Applicants have amended the specification to comply with 37 C.F.R. § 1.78.

Foreign priority date

On the Office Action Summary sheet, the Examiner acknowledges Applicants' claim for foreign priority under 35 U.S.C. § 119. The Examiner also notes that a certified copy of the priority document has not been received. Since the present application is a Rule 371 of PCT/JP99/01512, a certified copy of the priority document should be available from the PCT

branch. The Examiner is thus requested to contact the PCT branch, acquire a certified copy of the priority document, and acknowledge receipt of the same in the next Office Action.

Further, in order to perfect foreign priority, Applicants submit herewith a sworn English language translation of the priority document (JP10/100467, filed on March 27, 1998).

Elected claims

At page 2 of the Office Action, the Examiner acknowledges Applicants' election of **Group I**, claims 1-8 and 15-18. The Examiner confirms that claims 9-14 are withdrawn from examination as being directed to a non-elected invention. In the Election/Restriction requirement dated April 27, 2001, the Examiner defined Group I as claims 9-14 and Group II as claims 1-8 and 15-18. In response, on May 25, 2001, Applicants elected **Group II**, claims 1-8 and 15-18. In the Office Action, the Examiner correctly identifies the elected claims but has classified them as belonging to **Group I**.

In order to clarify the prosecution record, and to be sure that there is no misunderstanding, Applicants request that the Examiner verify that Applicants elected **Group II**, claims 1-8 and 15-18.

Claim rejections under 35 U.S.C. § 112, second paragraph

At page 2 of the Office Action, the Examiner rejects claims 15 and 16 under 35 U.S.C. § 112, second paragraph, as being dependent upon a non-elected base claim. In response, Applicants rewrite claim 15 in independent form, specifically, as new claims 20 and 21. Applicants respectfully request reconsideration and withdrawal of this aspect of the rejection.

Contrary to the Examiner's contention, present claim 16 is not dependent upon a non-elected base claim. Present claim 16 depends from pending claim 1. Therefore, Applicants respectfully request withdrawal of this aspect of the rejection regarding claim 16.

Claim rejections under 35 U.S.C. § 112 first paragraph

Claims 1-2, 4-8, and 15-17

At page 2 of the Office Action, the Examiner rejects claims 1-2, 4-8 and 15-17 under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner contends that Applicants have not enabled proteins that are deletion, substitution or addition mutants of SEQ ID NO:1. At page 4 of the Office Action, the Examiner states that Applicants have not shown that these proteins are capable of functioning with "p51 activity", nor provided guidance as to which proteins will exhibit the claimed biological activity.

The Examiner acknowledges that the specification enables proteins with transcriptional control, growth inhibition, and apoptosis induction activities. Thus, Applicants have amended claims 1 and 2 to replace the phrase "p51 activity" with "at least one activity selected from the group consisting of transcriptional control, growth inhibition and apoptosis induction". In addition, the specification provides sufficient guidance so that one skilled in the art would recognize which mutant proteins of SEQ ID NO:1 will retain these three claimed activities.

Applicants describe in the specification, and show in Figure 1, which regions of the amino acid sequence have specific biological activities. Applicants also describe, and show in Figures 1-4, the homology between the p51, p53 and p73 proteins. Applicants provide experimental data in the specification, in Examples 1, 2 and 4, to demonstrate that the p51 and p53 proteins share biological functions. Lastly, the p53 protein has been intensely studied and its

activities and functions are extremely well characterized. Thus, one of ordinary skill in the art could extrapolate from the teachings of the specification and from what is well known in the art to determine which mutant p51 proteins would be expected to retain the claimed transcriptional control, growth inhibition and apoptosis induction activities.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this aspect of the rejection, regarding claims 1-2.

Applicants have cancelled claim 4 and added new claim 19. This amendment essentially makes claim 4 dependent from claim 2 and incorporates the substitution of “transcriptional control, growth inhibition and apoptosis induction” activity for “p51 activity”. Based upon the amendment to claim 2 and the foregoing argument, Applicants respectfully request allowance of new claim 19.

Regarding the Examiner’s rejection of claims 5-8 and 15-17 under 35 U.S.C. § 112, first paragraph, Applicants have amended claims 5-8, claim 15 (deleted and set forth as new claims 20 and 21), and claim 16, for clarity and consistency, and in view of the Examiner’s rejection of claims 1-2, set forth below.

Claims 1-2

At page 4 of the Office Action, the Examiner rejects claims 1-2 under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner apparently contends that “a gene,” as defined at page 19 in the specification, includes double stranded *genomic* DNA.

Applicants have amended claims 1-2 to replace “A gene” with “An isolated DNA molecule”. Applicants have further amended claims 3, 4 (deleted and set forth as new claim 19),

5-8, 15 (deleted and set forth as new claims 20 and 21), and 16, to replace “gene” and “DNA” with “isolated DNA molecule.” Hence, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim rejections under 35 U.S.C. § 102

At page 5 of the Office Action, the Examiner rejects claims 1-2, 4-8, and 15-18 under 35 U.S.C. § 102(b) as being anticipated by Yang et al. (Mol. Cell 2:305-316). At page 6, the Examiner rejects the same claims under 35 U.S.C. § 102(e) as being anticipated by McKeon et al. (WO 99/19357). At page 7, the Examiner rejects claim 2 under 35 U.S.C. § 102(b) as being anticipated by Osada et al. (Nat. Med. 4(7):839-843).

Contrary to the Examiner’s contention, neither of these three references can be used to reject the claims under 35 U.S.C. § 102.

First, the Examiner has incorrectly cited both Yang et al. and Osada et al. under § 102(b) when in fact these two references could only possibly qualify under § 102(a). The significance of this difference is that Applicants can overcome a § 102(a) rejection by antedating the two cited references. The present application entered the U.S. National stage on **March 24, 1999** and is entitled to that date as its effective U.S. filing date. The relevant dates of the Examiner’s references are:

- Yang et al. published on **September, 1998**
- Osada et al. published on **July, 1998**.

Thus, these references were published less than one year before Applicants’ effective U.S. filing date and do not qualify under § 102(b).

In addition, Applicants claim the benefit of a foreign priority date of **March 27, 1998** based upon Japanese Application 10/100467. Thus, Applicants' foreign priority date antedates each of the two references. In order to perfect Applicants' claim to the foreign priority date and antedate the above references, Applicants submit herewith a sworn English language translation of Japanese Application 10/100467. Applicants believe that claims 1-2, 4-8, and 15-18 are fully supported by the Japanese Application.

Applicants respectfully request withdrawal of this rejection of the claims as being anticipated by Yung et al, and Osada et al, under 35 U.S.C. § 102(b).

Second, the Examiner is also incorrect in stating that McKeon et al. qualifies as a § 102(e) reference. The U.S. recently amended 35 U.S.C. § 102(e) to provide that, among other things, international application *publications* can be used as prior art based on their earliest effective filing date. However, amended § 102(e) is applied against applications filed on or after **November 29, 2000**. Applications filed prior to November 29, 2000 are subject to the former version of 35 U.S.C. § 102(e). The former version of § 102(e) requires that the cited reference is a *granted U.S. patent*.

Applicants are entitled to a filing date prior to November 29, 2000. The present application entered the U.S. National stage on **September 27, 2000**. Thus, the application must be examined under the former version of 35 U.S.C. § 102(e). Applicants do not believe that a U.S. patent has been granted from McKeon et al. and the Examiner has not indicated as such. Thus, McKeon et al. is not a reference under 35 U.S.C. § 102(e) and the Examiner has improperly rejected the present application based upon this reference.

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Applicants respectfully request withdrawal of the rejection of the claims as being anticipated by McKeon et al under 35 U.S.C. § 102(e).

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

At page 1, after the title, add:

-- The present application is the national stage under 35 U.S.C. § 371 of
PCT/JP99/01512, filed March 24, 1999. --

IN THE CLAIMS:

Claims 4, 9-15 and 18 are canceled.

The claims are amended as follows:

1. (Amended) An isolated DNA molecule ~~A gene~~-coding for the following protein (a) or
(b):
 - (a) a protein comprising ~~having the~~ amino acids 1- 448 of sequence shown under SEQ ID NO:
 - (b) a protein comprising ~~having an amino acid sequence derived from the~~ amino acids 1- 448 of
sequence shown under SEQ ID NO:1, with the proviso that said protein contains a ~~by~~ deletion,
substitution or addition of one or more ~~a plurality of~~ amino acids, and has at least one activity
selected from the group consisting of transcriptional control, growth inhibition and apoptosis
induction ~~having p51 activity.~~

2. (Amended) An isolated DNA molecule-A gene comprising the following DNA (a) or (b):
- (a) a DNA molecule comprising ~~having a nucleotide sequence identified by the nucleotides numbers 145-1488 of the nucleotide sequence shown under~~ SEQ ID NO:2
- (b) a DNA molecule which hybridizes under stringent conditions ~~capable of hybridizing with the DNA molecule comprising having a nucleotide sequence identified by the nucleotides numbers 145-1488 of the nucleotide sequence shown under~~ SEQ ID NO:2, ~~under stringent conditions and codes coding for a protein which has at least one activity selected from the group consisting of transcriptional control, growth inhibition and apoptosis induction~~ having p51 activity.
3. (Amended) The isolated DNA molecule-A gene as defined in ~~of~~ Claim 2, wherein said DNA molecule comprises ~~which has the nucleotides 1-2186 sequence of~~ shown under SEQ ID NO:2.
5. (Amended) An isolated DNA molecule-A DNA ~~characterized in that it is capable of hybridizing which hybridizes under stringent conditions with a DNA molecule comprising the nucleotides 1-2186 sequence of~~ SEQ ID NO:2 ~~under stringent conditions.~~
6. (Amended) An isolated DNA molecule-A DNA ~~characterized in that it is capable of the hybridizing which hybridizes under stringent conditions with a DNA molecule comprising a nucleotide sequence identified by the nucleotides numbers 145-1488 of~~ SEQ ID NO:2 ~~under stringent conditions.~~

7. (Amended) A DNA primer comprising the isolated DNA molecule ~~The DNA defined~~
~~in of Claim 5 for use as a primer.~~

8. (Amended) A DNA probe comprising the isolated DNA molecule ~~The DNA defined~~
~~in of Claim 5 for use as a probe.~~

16. (Amended) A vector comprising ~~harboring~~ the isolated DNA molecule ~~gene claimed~~
~~in of Claim 1.~~

Claims 19-21 are added as new claims.

19. (New) The isolated DNA molecule of Claim 2, wherein said DNA molecule is
cDNA.

20. (New) An isolated DNA molecule comprising a nucleotide sequence coding for a
polypeptide defined under (a) or (b) below:

(a) a polypeptide comprising amino acids 1-59 of SEQ ID NO:1

(b) a polypeptide comprising amino acids 1-59 of SEQ ID NO:1, with the proviso that said
polypeptide contains a deletion, substitution or addition of one or more amino acids, and has
transcriptional activation activity.

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21. (New) An isolated DNA molecule comprising a nucleotide sequence coding for a polypeptide defined under (a) or (b) below:

(a) a polypeptide comprising amino acids 142-321 of SEQ ID NO:1

(b) a polypeptide comprising amino acids 142-321 of SEQ ID NO:1, with the proviso that said polypeptide contains a deletion, substitution or addition of one or more amino acids, and has DNA binding activity.

22. (New) A method of producing a protein comprising at least one of

(a) amino acids 1-59 of SEQ ID NO: 1,

(b) amino acids 142-321 of SEQ ID NO: 1, and

(c) amino acids 359-397 of SEQ ID NO:1,

which comprises growing the host cell defined in Claim 17 in a culture medium and harvesting the protein from the resulting culture.